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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,933	11/20/2003	Jeffrey Roland Yon	JAB-1529-USACON2	5158

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EXAMINER	
JIANG, DONG	
ART UNIT	**PAPER NUMBER**
1646	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/22/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/718,933	YON ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3,8-10,19 and 20* is/are pending in the application.

4a) Of the above claim(s) *20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2, 3, 8-10 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Applicant's election without traverse of Group I invention, claims 2, 3, 8-10 and 19, filed on 02 October 2006 is acknowledged.

Currently, claims 2, 3, 8-10, 19 and 20 are pending, and claims 2, 3, 8-10 and 19 are under consideration. Claim 20 is withdrawn from further consideration as being drawn to a non-elected invention.

Formal Matters:

Priority acknowledgement

This application claims benefit of U.S. application 09/661,812 filed on 9/14/00, and U.S. provisional application 60/153,948 filed on 9/15/99, which is acknowledged.

Specification

Title

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are directed (i.e., nucleic acids).

Priority

This application lacks the necessary reference to the prior application. A statement reading "This is a continuation of Application No. 09/661,812, filed 9/14/00, now abandoned, which claims benefit of the provisional application 60/153,948 filed on 9/15/99." should be entered following the title of the invention or as the first sentence of the specification.

Claims

Claim 2 is objected to for the following informalities, appropriate correction is required for each item:

Claim 2 recites "An isolated nucleic acid *sequence*", however, it seems that the *product* of the nucleic acid is intended. "An isolated nucleic acid comprising the nucleotide sequence of SEQ ID NO:1" is suggested.

Rejections under 35 U.S.C. §101 and §112:

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 10 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 10, as written, does not sufficiently distinguish over cells as they may exist in a human body (in the potential in vivo gene therapy, for example, as indicated at page 7, [0093]) because the claims do not particularly point out any differences between the isolated product and a human body, which is not a patentable subject matter. The claims should be amended to indicate such a difference by insertion of "isolated" or "purified".

Claims 2, 3, 8-10 and 19 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 2, 3, 8-10 and 19 are directed to an isolated nucleic acid having SEQ ID NO:1, or encoding the polypeptide of SEQ ID NO:2, and a vector and a host cell thereof. Said polypeptide is a putative AchR α subunit as it shares 56% sequence identity with the α9 subunit and responds to Ach (specification page 10, the first paragraph), and it is designated subunit α10.

The specification discloses a nucleic acid (SEQ ID NO:1), which encodes a AchR subunit α10 (SEQ ID NO:2). The specification proposes that α10 contributes to cholinergic transmission both in the CNS and in certain non-neuronal tissures with importance to the hormonal and immunological status because of its unusual distribution and ability to co-assemble with α9 nAChR subunit (page 10, the first paragraph). The specification asserts utilities of said nucleic acids and polypeptides, including in tissue distribution studies (page 19, line 18), screening or identifying compounds for (page 23, line 32; page 32, line 8; and page 41) therapeutic uses such as those listed at page 42, immunoassays and detecting antibodies (page 24, lines 24 and 28),

generating antibodies (page 25). Further, the specification asserts that α10 subunit appears to be associated with leukocytes, and it is believed that there may be a significant association between α10 containing nAChR, leukocytes and activation processes leading to immunological or inflammatory events (page 40, lines 12-17).

The asserted utilities are not considered to be specific and substantial because the specification fails to disclose any particular gene mutation, or any disease or condition associated with the α10. The examples of electric current response of α9/α10 transfected cells to Ach or the inhibitor is noted in the specification (Figures 7-9). However, it is not clear what well-established utility is associated with the activity. Therefore, each of the disclosed utilities requires additional knowledge about the claimed nucleic acids and proteins encoded thereby before the DNA or proteins can be used for a specific purpose, such as those set forth in the specification. The disclosed uses in treatment and drug development are not specific and substantial, in the absence of knowledge of any disease or condition associated with inappropriate α10 activity or levels, which could be so treated. Therefore, there is no immediately evident patentable use for the α10. Upon further research, a specific and substantial utility might be found for the claimed isolated polynucleotide or protein. This further characterization, however, is part of the act of invention, and until it has been undertaken, the claimed invention is incomplete.

Use of a polynucleotide for tissue distribution studies, or a protein for generating antibodies is not considered by the Patent Office to be a specific or substantial utility in the absence of a specific use for such tissue distribution or antibodies, as such use could be asserted for *any* polynucleotide or protein.

The instant situation is analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-tumor activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention

must have either an immediately apparent or fully disclosed "real world" utility. The court held that:

> The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field. ... a patent is not a hunting license. ... [i]t is not a reward for the search, but compensation for its successful conclusion.

The instant claims are drawn to a polynucleotide encoding α10 polypeptide. There is no evidence of record or any line of reasoning that would support a conclusion that said α10 or modulatory agents thereof were, as of the filing date, useful for treatment of any disorders as stated at page 42 of the specification. Until some actual and specific relationship between gene mutations of α10 and diseases or conditions can be established, one of ordinary skill in the art would be required to perform additional experimentation in order to determine how to use the claimed invention. Thus, there was no immediately apparent or "real world" utility and the claimed invention is incomplete as of the filing date.

Applicants argument filed on 20 November 2003 in response to the Office Action for the parent application 09/661,812 (based on the similar rejection) has been fully considered, but is not deemed persuasive for reasons below.

At page 6 of the response, the applicant argues, citing MPEP, that the specification discloses a utility for the claimed invention as that α10 contributes to cholinergic transmission both in the CNS and in certain non-neuronal tissues with importance to the hormonal and immunological status of the organism. This argument is not persuasive because the specification does not disclose any specific functional activity or biological significance *directly* associated with the α10 subunit, which would provide "real world" use for the α10. As such, the claimed invention is not useful in its currently available form. According to MPEP, a utility that requires or constitutes carrying out further research to identify or reasonably confirm a "real world" context of use is not considered a substantial utility.

At pages 6-7 of the response, Applicants further argue, citing three US patents, that even if the exact function of the α10 subunit was unknown, the function of nicotinic acetylcholinergic receptors are members of the ligand-gated ion channel superfamily, and that one of skill in the art would readily have recognized the utility of studying any identified subunit of the receptor, and that the three US patentswould readily appreciate the utility of the claimed invention. This argument is not persuasive because, as indicated above, the use for the further study of the identified subunit itself does not constitute a substantial utility. MPEP indicates that *a "specific utility"* is specific to the subject matter claimed, this contrasts with a *general* utility that would be applicable to the broad class of the invention, and that labels such as "research tool," ... or "for research purposes" are *not helpful* in determining if an applicant had identified a specific and substantial utility for the invention (MPEP 2107.01, C.).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 3, 8-10 and 19 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9, 10 and 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is indefinite for the recitation "comprising a nucleic acid as defined in claim 8" because it is unclear to what it refers, as "a" indicates more than one. The replacement of "a" to

"the" would be remedial. Claim 10 is similarly indefinite for the recitation "carrying *a* vector according to claim 9".

Claim 19 recites the limitation "The DNA molecule of claim 8" in line 1. There is insufficient antecedent basis for this limitation in the claim. The claim is further indefinite for the recitation "a sequence *corresponding* to SEQ ID NO:2" because it is unclear what it is meant, for example, does it mean that the sequence is SEQ ID NO:2, comprising SEQ ID NO:2, or something else? The metes and bounds of the claim, therefore, cannot be determined.

Prior Art:

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Elgoyhen et al. (US5,683,912) discloses a nucleic acid, SEQ ID NO:1, which comprises a sequence encoding the present SEQ ID NO:2 with 57.2% homology (see computer printout of the search results).

Conclusion:

No claim is allowed.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Dong Jiang

Dong Jiang, Ph.D.
Patent Examiner
AU1646
12/14/06